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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/527,555   | 03/11/2005  | Max Werner Scheiwe   | 753-47 PCT/US       | 5860             |
| 23869 7590 05/13/2008<br>HOFFMANN & BARON, LLP<br>6900 JERICHO TURNPIKE<br>SYOSSET, NY 11791 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| SIMMONS, CHRIS E   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1612   |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/527,555

**Applicant(s)**

SCHEIWE ET AL.

**Examiner**

CHRIS E. SIMMONS

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11, 14-19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 10, 19 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11 and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

Applicants' arguments, filed 1/31/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 112 – 1<sup>st</sup> Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 11, and 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In this case, the newly amended independent claim 1 recites the limitation, "said preparation being substantially free of phospholipids". This introduces new matter to the disclosure as initially filed. There is no support in the initially filed disclosure for said

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limitation. It is acknowledged that paragraph [0042] of the instant specification states that:

[0042] "Phospholipids, e.g. lecithin, are unsuitable as surface-active solubilizers or as emulsifiers within the framework of the present invention",;

however, this is not support for "preparation being substantially free of phospholipids".

***Claim Rejections - 35 USC § 112 – 2<sup>nd</sup> Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11, and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 1 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Accordingly, it is unclear how "free of phospholipids" the claimed invention is required to be.

***Claim Rejections - 35 USC § 103***

Claim 1-9, 11, and 14-18 were rejected under 35 USC 103(a) as being unpatentable over **WO0016775** ('775) in view of **Jumaa et al.** ("Parental emulsions stabilized with a mixture of phospholipids and PEG-660-12-hydroxystearate: evaluation of accelerated and long-term stability"; European Journal of Pharmaceutics and Biopharmaceutics; 54; 2002:207-212.), US 4,931,285 ('285) and **STN REGISTRY DATA** for Miglyol 812 (1984). **This rejection is maintained.**

Applicant's arguments have been full considered but are not found to be persuasive.

Applicants are requesting reconsideration on the basis that the cited combination fails to suggest Applicants' claims, as amended. Applicants have amended claim 1 to read on compositions that are "optionally...substantially free of phospholipids". Applicants point to the instant disclosure at paragraph [0042] as being supportive of this newly claimed limitation and argues that since phospholipids are excluded from the composition. The new limitation does not alter the scope of the claims since it is optional; and is actually NOT excluded from the composition.

Applicants also argue that the oil-in-water (o/w) emulsions are not mentioned in '775 and that Jumaa et al. refers to different emulsion formulations in general, because o/w emulsions per se are intrinsically unstable. This is not persuasive because the o/w

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emulsion, contrary to Applicants' argument, *is* referred to in Jumaa et al. (See page 208;

*2.2 Experimental methods: 2.21. preparation of the emulsions*).

### ***Double Patenting***

Claims 1-9, 11, and 14-18 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, and 7-20 of U.S. Patent No. 6,492,395 in view of Jumaa et al. ("Parental emulsions stabilized with a mixture of phospholipids and PEG-660-12-hydroxystearate: evaluation of accelerated and long-term stability"; European Journal of Pharmaceutics and Biopharmaceutics; 54;2002:207-212.), US 4,931,285 ('285) and STN REGISTRY DATA for Miglyol 812 (1984). **This rejection is maintained.**

Applicants rely on their arguments made to the obviousness rejection outlined above in their traversal of the double patenting rejection. However, the arguments are not found to be persuasive for reasons set forth herein.

**No claims are allowed.**

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chris E Simmons/  
Examiner, Art Unit 1612

**/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612**